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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,571	02/08/2002	John P. McKearn	2789/6/US	1890

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,571	MCKEARN ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. The Amendment dated 11/16/04 has been entered into the record.

B. Claim 1 is pending in this Office Action and is the subject of this Office Action.

C. All Statutes not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Rejections - 35 USC § 112, first paragraph – new matter

A. The rejection of claim 1 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' arguments and, upon reading the specification, it is clear that all naturally occurring amino acid substitutions have been contemplated.

3. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claim 1 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' arguments that only two human IL-3 proteins were known at the time of filing (page 3, lines 11-21 of the specification).

4. Claim Rejections – Obviousness-Type Double Patenting

Upon further consideration, some obviousness-type double patenting rejections have been reinstated and new ones made. Many of the following rejections are based on the expectation that an increase in IL-3 activity would be concomitant with an increase in affinity of IL-3 for its receptor. In other words, the paragraph bridging pages 14-15 of the instant specification recites numerous functions of IL-3 and states "Many or all of these biological activities of hIL-3 involve signal transduction and high affinity receptor binding." Therefore, it would have been not only obvious at the time of the present invention, but an inherent property, that an increase in the functional ability of IL-3 receptors in these co-pending applications would lead to increased affinity. Applicant is reminded that those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970), MPEP § 804.

A. Claim 1 is rejected under the judicially created doctrine of double patenting over claim 1 of U. S. Patent No. 5,604,116 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Claim 1 of the instant invention recites a composition comprising a human IL-3 variant wherein Asp101 and/or Lys116 have been replaced by other amino acids. Claim 1 of the patent recites a mutant human IL-3 polypeptide which has a mutation at positions 101 (Ala) and 116 (Val). No activity is recited in the patent claims. However, since the required mutation of 101 and/or 116 is present in the patent claims, these mutants would be expected to have increased affinity. Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

B. Claim 1 is rejected under the judicially created doctrine of double patenting over claim 15 of U.S. Patent No. 5,677,149 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the patent recites that the IL-3 mutant has an increased proliferative activity. Since both the IL-3 of the patent and of the present application have substitutions at position 101, it would be expected that the compound would also have increased affinity.

C. Claim 1 is rejected under the judicially created doctrine of double patenting over claim 1 of U.S. Patent No. 6,153,183 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the patent recites that the IL-3 mutant has an increased proliferative activity. Since both the IL-3 of the patent and of the present application have substitutions at position 101 (Asn in the patent), it would be expected that the compound would also have increased affinity.

D. Claim 1 is rejected under the judicially created doctrine of double patenting over claim 1 of U.S. Patent No. 6,458,931 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The subject matter claimed in the instant application is fully disclosed in the patent

and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the patent recites that the IL-3 mutant has an increased proliferative activity. Since the IL-3 of the patent and present application have substitutions at position 101, it would be expected that the compound would also have increased affinity. Furthermore, the present claims recite "a composition comprising" so the claim reads on additional cytokines as recited in the patent claims.

E. Claim 1 is rejected under the judicially created doctrine of double patenting over claim 1 of U.S. Patent No. 5,817,486 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the patent recites that the IL-3 mutant has an increased proliferative activity. Since both the IL-3 of the patent and of the present application have substitutions at positions 101 and 116, it would be expected that the compound would also have increased affinity.

F. Claim 1 is provisionally rejected under the judicially created doctrine of double patenting over claim 24 of copending Application No. 08/466,631; claim 14 of 08/466,648; claim 40 of 08/468,588 and claim 24 of 08/469,317. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the paragraph bridging pages 14-15 of the instant specification recites numerous functions of IL-3 and states "Many or all of these biological activities of hIL-3 involve signal transduction and high affinity receptor binding." Therefore, it would have been not only obvious at the time of the present invention, but an inherent property, that an increase in the functional ability of IL-3 receptors in these co-pending applications would lead to increased affinity. Applicant is reminded that those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970), MPEP § 804.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

5. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Vadas et al. (U.S. Patent No. 5,591,427. Claim 1 of 5,591,427 recites essentially the same limitations as the present application. The only difference is that the present invention claims a composition. However, claim 9 of Vadas recites a pharmaceutical composition.

B. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Bauer et al. (U.S. Patent No. 5,677,149. The applied reference has 10 of 11 common inventors with the instant application (the exception being Pollazi). Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. The present invention is being given an effective filing date of 6/6/95 via U.S. Application No. 08/446,871. The patent is being given an effective filing date of 4/6/95.

Again, the paragraph bridging pages 14-15 of the instant specification recites numerous functions of IL-3 and states "Many or all of these biological activities of hIL-3 involve signal transduction and high affinity receptor binding." Therefore, it would have been not only obvious at the time of the present invention, but an inherent property, that an increase in the functional ability of IL-3 receptors in these co-pending applications would lead to increased affinity. Applicant is reminded that those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970), MPEP § 804.

6. Conclusion

A. Claim 1 is not allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 9 AM-6 PM (eastern); alt F 9 AM-6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman
Primary Examiner
Art Unit 1647

ROBERT LANDSMAN
PATENT EXAMINER